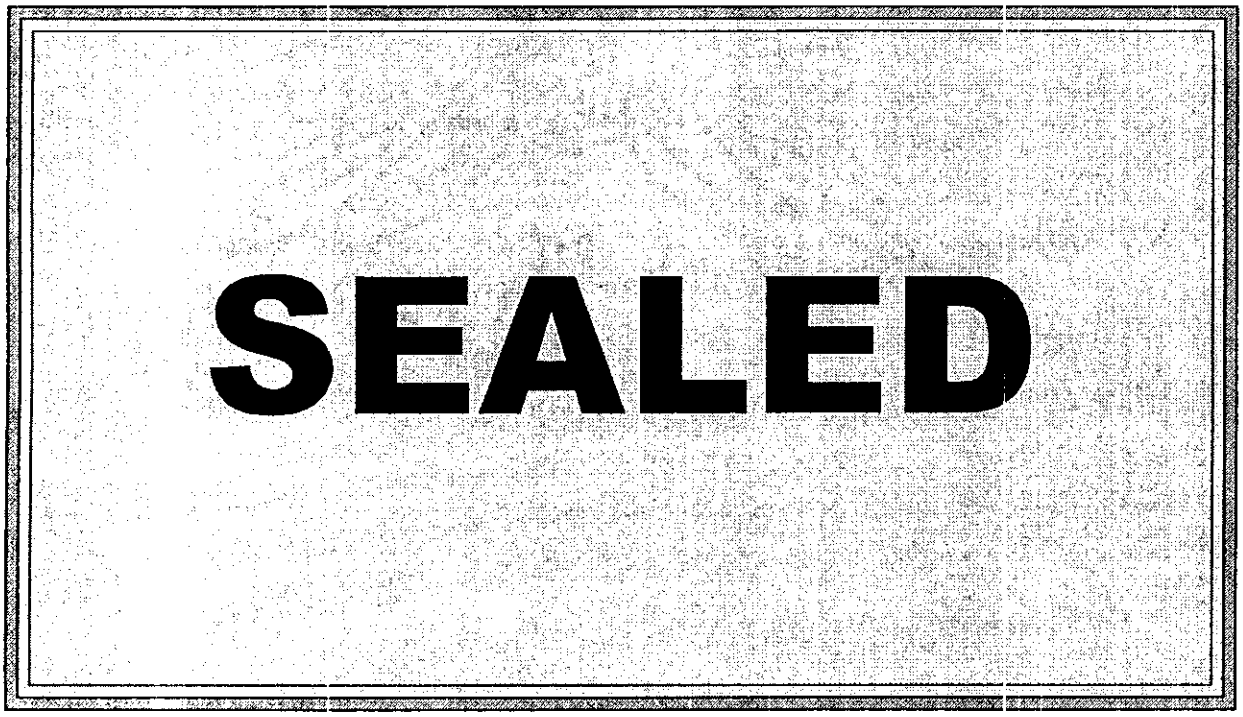

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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA
-oOo-

UNITED STATES OF AMERICA, PLAINTIFF, VS. STEPHEN LEE SELDON, M.D and DEBORAH MARTINEZ SELDON, DEFENDANTS.	CRIMINAL INDICTMENT **2:07-CR-0135-KJD-LRL** VIOLATIONS: 18 U.S.C. § 1341 - Mail Fraud 18 U.S.C. § 2- Aiding and Abetting 21 U.S.C. § 331(k) - Misbranding a Drug While Held for Sale 18 U.S.C. § 981(a)(1)(C) - Forfeiture

THE GRAND JURY CHARGES THAT:

At all times relevant to this Indictment:

Introduction

1. Defendant **STEPHEN LEE SELDON**, a medical doctor, schemed with defendant **DEBORAH MARTINEZ SELDON**, his wife and the manager of his medical practice, to defraud his patients by treating them with a cheaper, non-FDA approved version of Botox®, a drug used to reduce facial wrinkles. By misrepresenting to the patients of their medical practice the true nature of the product they were using, **STEPHEN LEE SELDON** and **DEBORAH MARTINEZ SELDON** enriched themselves while exposing patients to severe health risks.

Persons and Entities

2. **STEPHEN LEE SELDON** was a physician licensed by the State of Nevada to practice medicine.

3. **DEBORAH MARTINEZ SELDON** was the manager of **STEPHEN LEE SELDON'S** medical practice "A New You Medical Aesthetics" ("A New You"). As the office manager, **DEBORAH MARTINEZ SELDON'S** responsibilities included ordering supplies, paying bills, managing personnel and managing the bank accounts at A New You.

4. Together, **STEPHEN LEE SELDON** and **DEBORAH MARTINEZ SELDON** operated A New You in Las Vegas, Nevada. At A New You, **STEPHEN LEE SELDON** advertised that he performed wrinkle reducing treatments using injections of Botox®, and other cosmetic procedures.

Federal Regulation of Drugs and Biological Products

5. The FDA regulates the manufacture and distribution of drugs and biological products in the United States pursuant to the provisions of the Food, Drug and Cosmetic Act, Title 21, United States Code, Section 301, *et. seq.* (the "Act"). The FDA has established approval procedures for evaluating new drugs and licensing biological products. Approval is required for each new drug intended for human use before its introduction into interstate commerce is permitted. A license is also required for each new biological product before its introduction into interstate commerce is permitted.

6. A "drug" is defined by the Act as, among other things, any articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; articles (other than food) intended to affect the structure or any function of the body of man or other animals; and articles intended for use as a component of any such articles. 21 U.S.C. § 321(g).

7. A "biological product" is defined as a ". . . toxin applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i). When a biological product under this section also meets the definition of a "drug," as stated in Paragraph Five of this Indictment, the "biological product" is a "drug" under 21 U.S.C. § 321(g).

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8. The FDA enforces drug safety and efficacy standards by guarding against the misbranding of drugs. Pursuant to 21 U.S.C. § 331(k), the doing of any act with respect to a drug, if such act is done while the drug is held for sale (whether or not the first sale) after shipment in interstate commerce results in such drug being adulterated or misbranded, and is prohibited. 21 U.S.C. § 331(k).

9. A drug is misbranded if, among other things, it is offered for sale under the name of another drug. 21 U.S.C. § 352(i)(3).

Botulinum Neurotoxin Type A

10. The bacterium *Clostridium Botulinum* produces Botulinum Neurotoxin Type A, a highly potent toxin. When present in sufficient degree in humans, Botulinum Neurotoxin Type A can cause botulism. Severe botulism paralyzes its victims and can result in death unless timely medical intervention occurs

11. Botulinum Neurotoxin Type A can be both a drug under the Act, 21 U.S.C. § 321(g), and a biological product, 42 U.S.C. § 262(I), when the product is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings, or to affect the structure or the function of the human body. Therefore, no form of Botulinum Neurotoxin Type A can be distributed legally in interstate commerce for use on humans unless it has been approved by the FDA as a new drug (or there is in effect with the FDA a new drug application, an abbreviated new drug application, or a notice of claimed exemption for an investigational new drug), or it has been licensed as a biological product by the FDA.

Allergan Botox®

12 In or about December 1991, the FDA approved a biological products license for Botox®, the brand name of a drug derived from Botulinum Neurotoxin Type A, manufactured by Allergan, Inc., of Irvine, California, for the treatment of certain disorders of the muscles related to the eyes.

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13. In or about April 2002, the FDA approved a supplement to Allergan's Botox® license application for the treatment of glabellular lines, commonly referred to as forehead wrinkles. Under this FDA approval, Allergan's Botulinum Neurotoxin Type A product was marketed and labeled for this supplemental usage as Botox® Cosmetic.

14. Botox® and Botox® Cosmetic (collectively "Botox®") is injected with a hypodermic needle. It is used to temporarily smooth facial wrinkles. It works by paralyzing the muscles that cause wrinkles. Once injected, it blocks the transmission of nerve impulses to the muscles that receive the drug; this reduces the activity of the muscles that cause frown lines to form.

15. Botox® is the only product containing Botulinum Neurotoxin Type A approved by the FDA for the treatment of glabellular lines in humans. Allergan, Inc. ("Allergan") of Irvine, California is the only approved manufacturer of Botox®. Accordingly, all doctors treating patients with Botulinum Neurotoxin Type A are required to use Allergan's Botox® products.

Toxin Research International, Inc.

16. Toxin Research International, Inc. ("TRI") was an Arizona corporation with its principal place of business in Tucson, Arizona. TRI was managed and controlled by Chad Livdahl ("Livdahl") and Zahra Karim ("Karim").

17. During 2003 and 2004, TRI, through Livdahl and Karim, marketed and sold a Botulinum Neurotoxin Type A ("TRItox") that was neither approved nor licensed by FDA for use on humans.

18. Although TRI marketed its TRItox to physicians and others involved in patient treatments, it sold TRItox in vials that were labeled "For research purposes only, not for human use."

19. TRI's sales invoices, which accompanied orders of TRItox mailed to physicians and others involved in patient treatments, also included the warning, "For research purposes only, not for human use."

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20. TRI charged customers much less for its TRItox than Allergan charged customers for Botox®. By using TRItox instead of Botox®, physicians and others involved in patient treatments could increase their profits on each treatment.

COUNTS ONE THROUGH FOURTEEN
(Mail Fraud)

21. The Grand Jury incorporates by reference the allegations in Paragraphs One through Twenty, above, as though fully set forth herein.

22. From on or about October 15, 2003, until on or about September 16, 2005, in the State and Federal District of Nevada, and elsewhere,

STEPHEN LEE SELDON, MD and
DEBORAH MARTINEZ SELDON,

defendants herein, aided and abetted by each other, did devise and intend to devise a scheme and artifice to defraud, and for obtaining money and property by means of false and fraudulent pretenses, representations and promises, which scheme and artifice involved fraudulently obtaining money from patients by substituting cheaper, non-FDA approved TRItox in treatments provided to patients at A New You, while falsely and fraudulently representing to the patients that they were receiving injections of the more expensive, FDA-approved Botox®.

Scheme and Artifice to Defraud

23. It was part of the scheme and artifice that **STEPHEN LEE SELDON** and **Deborah Martinez Seldon** defrauded patients by misleading them to believe that they were receiving the FDA-approved drug Botox®, when, in fact, the patients were receiving TRItox, which was not FDA-approved and exposed the patients to severe health risks.

24. As part of the scheme and artifice, **Stephen Lee Seldon** and **Deborah Martinez Seldon** jointly operated A New You in Las Vegas, Nevada, at which they offered and advertised Botox® injections.

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25. As part of the scheme and artifice, **STEPHEN LEE SELDON** and **Deborah Martinez Seldon** caused advertisements to be placed in local magazines, such as "Fun & Fit", "QVegas" and "The Phillipine Times," which would offer "BOTOX $8 PER UNIT." The typical advertisement, which is substantially similar to the following, would represent that:

> "...Dr. Seldon is Board Certified and has been specially trained by Allergan for all your Botox needs."

The typical advertisements would further state,

> "Don't be fooled by Botox prices by the 'area', wrinkles vary in size and depth. Each patient at [A New You] is charged by the unit & the amount of Botox needed for their treatment. Botox is always mixed per Allergan Standards."

These advertisements sought to create the false impression that **STEPHEN LEE SELDON** was using Allergan's Botox® for the treatment of his patient's wrinkles when, in fact, he was not.

26. As part of the scheme and artifice, **STEPHEN LEE SELDON** and **DEBORAH MARTINEZ SELDON** caused Botox® promotional materials to be displayed and distributed to prospective patients at A New You, when, in fact, patients were not receiving FDA-approved Botox®.

27. As part of the scheme and artifice, **STEPHEN LEE SELDON** and **DEBORAH MARTINEZ SELDON** caused a certificate to be displayed on the wall at A New You which identified **STEPHEN LEE SELDON** as having been trained in the application of Botox®, when, in fact, **STEPHEN LEE SELDON** had never attended any training sessions sponsored by Allergan and has no Allergan-approved training in the use of Botox®.

28. As part of the scheme and artifice, **STEPHEN LEE SELDON** and **DEBORAH MARTINEZ SELDON** caused patients to sign consent forms prior to receiving cosmetic procedures. These patient consent forms fraudulently represented that the defendant intended to use Botox® on the patients completing the form when, in fact, **STEPHEN LEE SELDON** knew he was going to inject his patients with TRItox.

. . .

29. As part of the scheme and artifice, **STEPHEN LEE SELDON** and **DEBORAH MARTINEZ SELDON** ordered and caused to be ordered thirty-eight (38) 500 I.U. vials of TRItox between October 2003 and September 2004. **STEPHEN LEE SELDON** and **DEBORAH MARTINEZ SELDON** paid $36,925 for a total of 19,000 units (38 vials @ 500 units per vial) of TRItox, approximately half of what Allergan would have charged for an equivalent amount of Botox®.

30. As part of the scheme and artifice, **STEPHEN LEE SELDON** and **DEBORAH MARTINEZ SELDON** stopped purchasing Botox® from Allergan in October 2003, the same month they began purchasing or causing to be purchased TRItox from TRI.

31. As part of the scheme and artifice, **STEPHEN LEE SELDON** spoke at a seminar in Scottsdale, Arizona, in September 2004, sponsored by TRI, in which he promoted the use of TRItox and claimed that he used it on patients in his practice, notwithstanding the warning on each vial that TRI was for "Research purposes only, not for human use."

32. In late November, 2004, the national media publicized the hospitalization of four individuals who had contracted botulism after receiving injections of a non-FDA approved botulinum toxin at an unrelated medical clinic in Florida. Less than two months later, in January 2005, as part of the scheme and artifice, **DEBORAH MARTINEZ SELDON** arranged for a secret purchase of, and received, 132 additional vials of TRItox for $50,000 for use by **STEPHEN LEE SELDON** at A New You.

33. As part of the scheme and artifice, **STEPHEN LEE SELDON** and **Deborah Martinez Seldon** failed to disclose to A New You's patients that:

a. They were being injected with a different drug than Botox®;

b. The product they were being injected with was not approved by the FDA; and

c. They were being injected with a drug labeled "For research purposes only, not for human use."

34. As part of the scheme and artifice, **STEPHEN LEE SELDON** and **DEBORAH MARTINEZ SELDON** took steps to conceal their fraudulent use of TRItox, as follows:

a. On or about January 12, 2005, **DEBORAH MARTINEZ SELDON** caused to be falsified A New You's computerized medical records by deleting references to "Botox®." and changing these entries to the generic notation "Cosmetic Procedure;"

b. On or about September 16, 2005, **STEPHEN LEE SELDON** and **DEBORAH MARTINEZ SELDON** caused twenty-eight (28) vials of TRItox to be returned to the FDA. **STEPHEN LEE SELDON** and **DEBORAH MARTINEZ SELDON** sought to create the misleading impression that they were returning 28 vials of the original 38 vials purchased from TRI. In fact, **STEPHEN LEE SELDON** and **DEBORAH MARTINEZ SELDON** had used all of the original TRItox on the patients at A New You, and were returning vials that were part of **DEBORAH MARTINEZ SELDON's** secret purchase of 132 vials from TRI in January 2005.

35. On or about the dates set forth below, in the State and Federal District of Nevada and elsewhere,

STEPHEN LEE SELDON, MD and
DEBORAH MARTINEZ SELDON,

defendants herein, aided and abetted by each other, for the purpose of executing the scheme and artifice, did knowingly cause packages containing vials of TRItox, to be delivered by United Parcel Service ("UPS"), a private and commercial interstate carrier, according to the directions thereon, from TRI in Arizona to **STEPHEN LEE SELDON** and **DEBORAH MARTINEZ SELDON** in Las Vegas, Nevada, as more specifically described below, with each delivery constituting a separate violation of Title 18, United States Code, Sections 1341 and 2:

Count	Date of Shipment by UPS (on or about)	Description of Matter Delivered by UPS
1	November 15, 2003	Two vials of TRItox
2	November 29, 2003	Two vials of TRItox
3	January 10, 2004	Two vials of TRItox
4	January 31, 2004	Two vials of TRItox
5	March 6, 2004	Two vials of TRItox
6	March 27, 2004	Two vials of TRItox
7	April 3, 2004	Two vials of TRItox
8	May 1, 2004	Two vials of TRItox
9	June 12, 2004	Two vials of TRItox
10	June 26, 2004	Two vials of TRItox
11	July 10, 2004	Two vials of TRItox
12	August 7, 2004	Two vials of TRItox
13	August 14, 2004	Four vials of TRItox
14	September 18, 2004	Ten vials of TRItox

COUNT FIFTEEN
(Misbranding a Drug While Held for Sale)

36. The Grand Jury incorporates by reference the allegations in Paragraphs One through Thirty-Five, above, as though fully set forth herein.

37. From on or about October 15, 2003, and continuing through on or about September 16, 2005, in the State and Federal District of Nevada, and elsewhere,

STEPHEN LEE SELDON, MD and
DEBORAH MARTINEZ SELDON,

defendants herein, with the intent to defraud and mislead, did engage in various acts, and did cause each other and others to engage in various acts, which acts resulted in a drug being misbranded, as

defined at 21 U.S.C. § 352(l), while such drug was held for sale after shipment in interstate commerce, in that the defendants **STEPHEN LEE SELDON** and **DEBORAH MARTINEZ SELDON,** offered TRItox, a drug, for sale by injection to patients under the name of a different drug, Botox®, which they knew to be an FDA approved drug sold by Allergan; all in violation of 21 U.S.C. §§ 331(k) and 333(a)(2) and 18 U.S.C. § 2.

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FORFEITURE ALLEGATION
(Mail Fraud)

1. The allegations contained in Counts One through Thirty-Five of this Criminal Indictment are hereby realleged and incorporated herein by reference for the purpose of alleging forfeiture pursuant to the provisions of Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c).

2. Upon a conviction of the felony offenses charged in Counts One through Fourteen of this Criminal Indictment,

STEPHEN LEE SELDON, MD and
DEBORAH MARTINEZ SELDON,

defendants herein. shall forfeit to the United States of America any property, real or personal, which constitutes or is derived from proceeds traceable to violations of Title 18, United States Code, Section 1341, a "specified unlawful activity" as defined in Title18, United States Code, Sections 1956(c)(7)(A) and 1961(1)(B), up to $144,000.00 in United States Currency.

3. If any property being subject to forfeiture pursuant to Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c), as a result of any act or omission of the defendant -

1. cannot be located upon the exercise of due diligence;
2. has been transferred or sold to, or deposited with, a third party;
3. has been placed beyond the jurisdiction of the court;
4. has been substantially diminished in value; or
5. has been commingled with other property that cannot be divided

without difficulty; it is the intent of the United States of America, pursuant to Title 21, United States Code, Section 853(p), to seek forfeiture of properties of the defendant up to $144,000.00 in United States Currency.

. . .

All pursuant to Title 18, United States Code, Section 981(a)(1)(C), Title 28, United States Code, Section 2461(c), and Title 21, United States Code, Section 853(p).

DATED: this 27TH date of June 2007

A TRUE BILL:

/S/
FOREPERSON OF THE GRAND JURY

STEVEN W. MYHRE
Acting United States Attorney

CRANE M. POMERANTZ
Assistant United States Attorney